

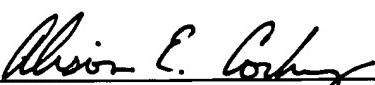
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 112981.126US1 U.S. APPLICATION NO. (if known, see 37 CFR 1.5) TBA 107538991
INTERNATIONAL APPLICATION NO. PCT/US2003/041392	INTERNATIONAL FILING DATE 22 December 2003	PRIORITY DATE CLAIMED 20 December 2002
TITLE OF INVENTION HIGH PRESSURE COMPACTION FOR PHARMACEUTICAL FORMULATIONS		
APPLICANT(S) FOR DO/EO/US SMITH, Thomas J., GAUZER, Gene		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. <input checked="" type="checkbox"/> The US has been elected (Article 31). <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). <p>Items 11 to 20 below concern document(s) or information included:</p> <ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). <ol style="list-style-type: none"> 1.) Petition to Correct Priority Under 37 CFR 1.182 2.) International Search Report for PCT/US2003/041392 20. <input checked="" type="checkbox"/> Other items or information: 		

This collection of information is required by 37 CFR 1.414 and 1.491-1,492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) TBA 10/538991		INTERNATIONAL APPLICATION NO. PCT/US2003/041392		ATTORNEY'S DOCKET NUMBER 112981.126US1	
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21. <input checked="" type="checkbox"/> Basic national fee.....				\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... All other situations.....				\$ 200.00	
23. <input checked="" type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... International Search Report prepared and provided to the Office..... All other situations.....				\$ 100.00	
TOTAL OF 21, 22 and 23 =				\$ 600.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)		RATE	
28	- 100 = 0	/50 =		x \$250	\$
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).				\$	
CLAIMS		NUMBER FILED	NUMBER EXTRA	RATE	\$
Total claims		- 20 =		x \$ 50	\$
Independent claims		- 3 =		x \$200	\$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$360	\$
TOTAL OF ABOVE CALCULATIONS =				\$ 600.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.					
				SUBTOTAL =	\$ 300.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
				TOTAL NATIONAL FEE =	\$ 300.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
				TOTAL FEES ENCLOSED =	\$ 300.00
				Amount to be refunded:	\$
				Amount to be charged:	\$ 300.00
a. <input type="checkbox"/>	A check in the amount of \$ _____ to cover the above fees is enclosed.				
b. <input checked="" type="checkbox"/>	Please charge my Deposit Account No.08-0219 in the amount of \$ 300.00 to cover the above fees. A duplicate copy of this sheet is enclosed.				
c. <input checked="" type="checkbox"/>	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No.08-0219. A duplicate copy of this sheet is enclosed.				
d. <input type="checkbox"/>	Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.				
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.					
SEND ALL CORRESPONDENCE TO:					
Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109 (617) 526-6000 (617) 526-5000 (Facsimile)					
 SIGNATURE Alison E. Corkery NAME 52,770 REGISTRATION NUMBER					



107538991
JC09 Rec'd PCT/PTO 15 JUN 2005

Commissioner for Patents
 Washington, DC 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
60/435,448	12/20/2002	80		TJS-007			

CONFIRMATION NO. 2387

Lisa M. Portscher
 15 Braeburn Road
 Hyde Park, MA 02136

FILING RECEIPT

OC000000009576584

Date Mailed: 02/28/2003

Receipt is acknowledged of this provisional Patent Application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Thomas J. Smith, Weston, MA;

If Required, Foreign Filing License Granted: 02/27/2003

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Large crystalline formulations for sustained release delivery of anti-Parkinson agents

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING

"LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

101538991

JC09 Rec'd PCT/PTO 15 JUN 2005

VERIFICATION OF MAILING BY EXPRESS MAIL

I, LISA M. PORTSCHER, state that I have mailed the documents identified on the attached Transmittal Form/Cover Sheet to the U.S. Patent and Trademark Office, addressed to the Commissioner for Patents, Washington, D.C. 20231, via Post Office to Addressee, Label No. EU 792050075, at the HYDE PARK, MA Post Office. I have made this verification after depositing the correspondence, but within one business day after depositing the correspondence.

EU 792050075 US

Lisa M Portscher
(Signature)

Date of Signature: 12/20

Time of Signature: 11:30 AM

Date of Deposit: 12/20

Time of Deposit: 10:34 AM

Re: Application Number: Unknown

Filing Date: 12/20/02

Title: Large Crystalline Formulations for Sustained Release Delivery of Anti-Parkinson Agents

First Named Inventor: Smith, Thomas J.

Attorney Docket Number: TJS - 007

Filed by: Lisa M. Portscher

10/538991

PTO/SB/16 (10-01)

Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

EV792050075

JC09 Rec'd PCT/PTO 15 JUN 2005

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Thomas J.	Smith	Weston, MA

Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

*Large Crystalline Formulations for Sustained Release
Delivery of Anti-Parkinson Agents*

Direct all correspondence to:

CORRESPONDENCE ADDRESS

Customer Number



OR

Type Customer Number here

<input checked="" type="checkbox"/> Firm or Individual Name	Lisa M. Portscher					PATENT TRADEMARK OFFICE
Address	15 Braeburn Road					
Address						
City	Hyde Park	State	MA	ZIP	02136	
Country	USA	Telephone	617-361-5434	Fax		

ENCLOSED APPLICATION PARTS (check all that apply)

Specification Number of Pages

 16

CD(s), Number

Drawing(s) Number of Sheets

Other (specify)

Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

Applicant claims small entity status. See 37 CFR 1.27.

FILING FEE AMOUNT (\$)

A check or money order is enclosed to cover the filing fees

The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:

\$80.00

Payment by credit card. Form PTO-2038 is attached.

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

No.

Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE

TYPED or PRINTED NAME Lisa M. Portscher

TELEPHONE 617-361-5434

Date

12/20/02

REGISTRATION NO.
(if appropriate)
Docket Number:

N/A

TJS-007

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

10/538991
JC09 Rec'd PCT/PTO 15 JUN 2005

PTO/SB/17 (10-02)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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FEE TRANSMITTAL for FY 2003

Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27
TOTAL AMOUNT OF PAYMENT (\$)
80.00**Complete if Known**

Application Number	Unknown
Filing Date	12/20/2002
First Named Inventor	Smith, Thomas J.
Examiner Name	Unknown
Art Unit	Unknown
Attorney Docket No.	TJS - 007

METHOD OF PAYMENT (check all that apply)
 Check Credit card Money Order Other None

 Deposit Account:

Deposit Account Number	<input type="text"/>
Deposit Account Name	<input type="text"/>

The Commissioner is authorized to: (check all that apply)

- Charge fee(s) indicated below Credit any overpayments
 Charge any additional fee(s) during the pendency of this application
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION**1. BASIC FILING FEE**

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 740	2001 370	Utility filing fee	<input type="text"/>
1002 330	2002 165	Design filing fee	<input type="text"/>
1003 510	2003 255	Plant filing fee	<input type="text"/>
1004 740	2004 370	Reissue filing fee	<input type="text"/>
1005 160	2005 80	Provisional filing fee	80.00
SUBTOTAL (1)		(\$)	80.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Independent Claims	Multiple Dependent	Extra Claims	Fee from below	Fee Paid
			-20** =	<input type="text"/> X <input type="text"/> = <input type="text"/>	<input type="text"/>
			-3** =	<input type="text"/> X <input type="text"/> = <input type="text"/>	<input type="text"/>
				0	= 0

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 84	2201 42	Independent claims in excess of 3
1203 280	2203 140	Multiple dependent claim, if not paid
1204 84	2204 42	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent
SUBTOTAL (2)		(\$) 0.00

** or number previously paid, if greater; For Reissues, see above

3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	<input type="text"/>
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	<input type="text"/>
1053 130	1053 130	Non-English specification	<input type="text"/>
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	<input type="text"/>
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	<input type="text"/>
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	<input type="text"/>
1251 110	2251 55	Extension for reply within first month	<input type="text"/>
1252 400	2252 200	Extension for reply within second month	<input type="text"/>
1253 920	2253 460	Extension for reply within third month	<input type="text"/>
1254 1,440	2254 720	Extension for reply within fourth month	<input type="text"/>
1255 1,960	2255 980	Extension for reply within fifth month	<input type="text"/>
1401 320	2401 160	Notice of Appeal	<input type="text"/>
1402 320	2402 160	Filing a brief in support of an appeal	<input type="text"/>
1403 280	2403 140	Request for oral hearing	<input type="text"/>
1451 1,510	1451 1,510	Petition to institute a public use proceeding	<input type="text"/>
1452 110	2452 55	Petition to revive - unavoidable	<input type="text"/>
1453 1,280	2453 640	Petition to revive - unintentional	<input type="text"/>
1501 1,280	2501 640	Utility issue fee (or reissue)	<input type="text"/>
1502 460	2502 230	Design issue fee	<input type="text"/>
1503 620	2503 310	Plant issue fee	<input type="text"/>
1460 130	1460 130	Petitions to the Commissioner	<input type="text"/>
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	<input type="text"/>
1806 180	1806 180	Submission of Information Disclosure Stmt	<input type="text"/>
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	<input type="text"/>
1809 740	2809 370	Filing a submission after final rejection (37 CFR 1.129(a))	<input type="text"/>
1810 740	2810 370	For each additional invention to be examined (37 CFR 1.129(b))	<input type="text"/>
1801 740	2801 370	Request for Continued Examination (RCE)	<input type="text"/>
1802 900	1802 900	Request for expedited examination of a design application	<input type="text"/>
Other fee (specify)			<input type="text"/>
*Reduced by Basic Filing Fee Paid		SUBTOTAL (3)	(\$) 0.00

(Complete if applicable)

Name (Print/Type)	Lisa M. Portscher	Registration No. (Attorney/Agent)	N/A	Telephone	617-361-5434
Signature			Date	12/20/02	

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



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The following have been received by the U.S. Patent and Trademark Office on the date stamped hereon:

Patent Application Transmittal Form

- Non-Provisional Provisional Design CPA of # _____ Reissue of # _____
 Divisional, Continuation, or C-I-P of Prior App. # _____
 Fee Transmittal Form \$ 80.00
 Applicant claims small entity status
 Specification (Total Pages 16)
 Drawing(s) (Total Sheets _____)
 Formal Informal
 Oath or Declaration (Total Pages _____)
 Newly executed original copy
 Copy from a prior application
 Deletion of Inventors
 Application Data Sheet
 CD-ROM or CD-R in duplicate, large table or
Computer Program

- Assignment Papers (coversheet and documents)
- 37 CFR 3.73(b) Statement
- Power of Attorney
- English Translation Document
- Information Disclosure Statement, PTO-1448
and _____ copies of IDS Citations
- Preliminary Amendment
- Certified Copy of Priority Document
- Nonpublication Request under 35 U.S.C.
122(b)(2)(B)(i)
- Nucleotide and/or Amino Acid Sequence
Submission
- Computer Readable Form (CRF)
- Specification Sequence Listing on:
 CD-ROM or CD-R (2 copies); or
 Paper
- Statements verifying identity of above
copies

J1046 U.S. PTO

60/435448



12/20/02

Title: Large Crystalline Formulations for Sustained Release Delivery
of Anti-Parkinson Agents

1st Inventor: Smith, Thomas J.

Filed by: Lisa M. Potscher

Date Mailed: 12/20/02

Express Mail Label No: EU792050075

Attorney Docket No: TJS-007